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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,762	04/09/2001	Daniela Tomese Buonamassa	CHIR-0311	7831

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EXAMINER	
SALIMI, ALI REZA	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,762	BUONAMASSA ET AL.	
	Examiner	Art Unit	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-37 and 39-51* is/are pending in the application.

4a) Of the above claim(s) *2-5,7-9,15-37 and 39-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10-14,50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed 10/11/2005. Claims 1-5,7-37, and 39-51 are pending. Claims 2-5, 7-9, 15-37, and 39-49 have been withdrawn from consideration for reasons of record as being drawn to the non-elected inventions. Claims 1, 10-14, 50 and 51 are under consideration.

Please note any ground of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicants in previously filed paper of 6/10/2005 elected invention of Group II (claims 1, 10-14, 50 and 51) without traverse (emphasis added). Applicants, after receiving the first office action on the merits mailed 7/6/05, are now asking the Office to revisit the issue of restriction again and rejoin all the previously restricted groups, and are now asserting the unity of invention exists among all groups. Applicants' argument as part of amendment filed 10/11/05 has been considered fully, but they are not persuasive. First, the election of Group II was made without traverse and is Final. Second, Applicants should have presented any concern prior to receiving the Office Action, and not after. Office is not under obligation to keep visiting issues that were clearly resolved. Applicants are asking the Office to in effect examine the entire case, regardless of valid restriction requirement or not, this is not permitted. Moreover, the reference cited in the written restriction clearly indicated that Applicants' application lacked unity of invention, which Applicants did not present any opposing argument against. Still further, claim

12 was and is examined within the scope of elected Group II, and claim 9 is not rejoined because Applicants opted to choose Group II to be examined. Regarding the method claim(s), i.e. claim 15, the claim(s) remain withdrawn until such time when the product of Group II maybe found allowable, then they can be rejoined, assuming claim(s) is/are enabled and free of art. Therefore, only claims of Group II (claims 1, 10-14, 50 and 51) per Applicants' own election without traverse are under consideration.

Applicants are reminded to cancel the claims to the non-elected Group(s).

Due to Applicants' amendment to the claims the nature of invention is now changed and the previously cited rejections are no longer applicable and are herewith withdrawn.

New grounds of rejection follow:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 10-12, 50, and 51 rejected under 35 U.S.C. 102(e) as being anticipated by Lowy et al (US Patent NO. 5,855,891 A).

The above-cited patent teaches the product that is being claimed. Lowy et al taught fusion of chimeric protein comprising capsid proteins of two different viruses, namely human papillomavirus HPV-16, and bovine papillomavirus BPV-1 L1 capsid proteins (see the claims). The product as taught by Lowy et al inherently forms VLPs as it is well known in the art that papillomavirus L1 capsid protein on its own forms VLPs. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Also, claiming of a new use, i.e., induction of immune response, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Applicants are reminded that the intended use of a product does not carry patentable weight. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey, 152 USPQ 235 (CCPA 1967); In re Otto, 136 USPQ 458, 459 (CCPA 1963); and In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 10-14, 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowy et al (US Patent NO. 5,855,891 A), and Ott et al, (Vaccine Design, 1995, pages 277-296).

As stated above Lowy et al taught a composition comprising of virus like particles (VLP) with at least two types of viruses, namely HPV-16 L1 and BPV-1 L1 proteins (see the claims). This differs since they did not add a well-known adjuvant to their composition.

Ott et al taught adjuvant design to be utilized in vaccines. Additionally, they taught employment of MF59 adjuvant along with various human virus antigens including papillomavirus, wherein the efficacious results were observed (see page 282, 1st full paragraph, and Figure 4).

Therefore, one of ordinary skill in the art at the time of filing would have been highly motivated to mix the product taught by Lowy et al with adjuvant taught by Ott et al to obtain enhanced immune response. Utilizing adjuvant to enhance immune response is notoriously routine in this art. One of ordinary skill in the art being familiar with the above state of the would not have anticipated any unexpected results. Thus, the claimed invention as a whole is prima facie obvious absent unexpected results.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

12/30/2005

ALI R. SALIMI
PRIMARY EXAMINER